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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,681	01/18/2001	Markus Haller	P-9418	6923

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EXAMINER	
PRIETO, BEATRIZ	

ART UNIT	PAPER NUMBER
2142	

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/764,681	HALLER ET AL.	
	Examiner	Art Unit	
	Prieto B.	2142	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to RCE/Amendment filed 06/28/05, claims 1 and 29 have been amended, claims 56-59 were canceled previously, claims 1-55 remain pending.

2. Quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejection set forth in this office action may be found in previous office action.

3. Claims 1-2, 5, 7, 8, 10-22, 24-26, 28-30, 32-35, 37-49, 51-53, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, Jr. et. al. (US 5,456,692) (Smith hereafter) in view of Nappholz et. al. (US 5,720,770) (Nappholz hereafter) in further view of Cox et. al. (US 5,383,912) (Cox hereafter)

Regarding claim 1, Smith teaches substantial features of the invention as claimed, including a system (Figs. 1 and 5-6) for monitoring the performance of pacemaker (20 of Fig. 1) (IMD) implanted within a body of a patient (col 6/lines 35-39 and col 10/line 35-47), or monitoring the health of the patient (col 9/lines 54-58 and col 7/lines 3-23), the system comprising:

the IMD (20) being capable of bi-directional communication link (44) with a external programmer (46) ("communication module") located external to the patient's body (see Figs. 1 and 6);

the IMD (20) comprising a memory (40) having software loaded therein (Figs. 5-6) and for loading software from the communication module (46) (col 20/lines 27-30);

means for permitting the software to be updated (steps on Figs. 3-4) (col 5/lines 23-44, col 9/lines 6-24) after the IMD has been implanted within the patient's body (col 4/lines 5-22, 28-37, 50-60);

the communication module (46) comprising means for updating software loaded in the IMD (Figs. 3-4, col 5/lines 21-34, col 4/lines 5-13 or col 11/lines 51-54);

a remote computer system (64 of Fig. 6) capable of initiating the downloading of updated or new software to the IMD (20) via the communication module (46) (col 14/lines 44-51, update software steps of Figs. 3-4 or new software steps of Fig. 11 and col 20/lines 50-53); however Smith is silent regarding the use of a mobile telephone;

Nappholz teaches a system/method for remotely delivering therapy to a patient through an implanted medical device (abstract), the system including an implantable medical device (ICD-12) having a bi-directional communication link (24) with a communication module (14) located external to the patient's body (Fig. 1) (col 3/lines 61-col 4/line 9 and col 5/lines 15-18);

the communication module (14) including a mobile telephone and repeater, capable of receiving and transmitting information via a communication network (26 and 30) (col 4/lines 6-11, 16-20 and col 5/lines 20-25); and

a communication system (26 or 8) capable of bi-directional communication with the mobile phone (14) and a remote computer system (27) (col 4/lines 6-20) and supporting communication between the remote computer system (27) to the IMD (12) through the communication module (14) via said communication system (26) comprising: a standard cellular telephone communication system (col 6/lines 64-col 7/line 3, 23-27, 38-44, 50-52, 59-64). One ordinary skilled in the art would recognize that a cellular communication system is capable of performing simultaneous bi-directional communication, specifically, cellular communications system using a base station(s) and distributed antenna units, describe by Nappholz, enable a plurality of two-way inbound/outbound cellular telephone transmissions between a base station using a set of RF channels. The respective RF outbound signal are broadcasted directly to mobile units in the cell, the remote cell receives a plurality of simultaneous inbound telephone transmissions from the mobile units as an RF analog inbound signal;

the remote computer system (27) couples to a "emergency dispatch" facility (29) as shown on Fig. 1; although Nappholz teaches where the IMD is capable of bi-directional communication with an external communication module, it does not teach where this communication is simultaneous.

Cox teaches an implantable medical device capable of simultaneous bi-directional communication with a communication module located external to the patient's body (col. 2, lines 32-43 & col. 5, lines 12-39).

It would be obvious to one ordinary skilled in the art at the time the invention was made given the teachings of Smith for updating and replacing software programs on an implanted medical device from a remote computer system through a communication module and the suggestion of using telephone base communication medium, associated procedures and protocols for establishing said communication, the teachings of Nappholz having the same intended purpose would be readily apparent. Given the teaches of Nappholz for providing communication in any combination between the implanted device, the patient, the physician or health care provider facility and personnel using an external module comprising multiple components each providing their intrinsic functions, yet configured to communicate with each other, one ordinary skilled would motivation to apply the teachings of the Nappholz because in doing so the patient is provided with full mobility, and further both the patient and the device can communicate with a remote physician, hospital or care facility using commercially available communication technology. One would be further motivated to combine the teachings of Cox with Smith for the purposes of providing a high

speed data communication arrangement that shifts the burden of extra power consumption away from the implantable device to the external device, as suggested by Cox.

Regarding claim 2, wherein the communication module incorporates the mobile telephone (Nappholz: 14 of Fig. 1, see col 5/lines 20-25).

4. Claims 3-4 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Nappholz in further view of U.S. Patent No. 5,497,339 Bernard.

Regarding claims 3-4, however the Smith nor Nappholz references teach the integration of a personal mobile telephone with a personal digital assistant or their separation into separate devices.

Bernard teaches the multiple integration of functional capabilities to a PDA, teaching a PDA with cellular phone capabilities (col 1/lines 39-57, col 3/line 49-col 4/line 16) and include switching communication function for switching data between cellular and telephone communication links and necessary supporting data conversions/circuitry rx-tx functions (col 16/lines 38-65) associated including the capability to remotely download software to the integrated unit (Fig. 9A).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the Smith suggestions of using a Personal Communication Network (PCN) for interrogating the implanted device to assess its operation or the patient's health through the communication module (14). One ordinary skilled would be motivated to utilize Bernard teachings for combining telephone and personal communication devices, such as PDA functionalities because in doing so the patient can further schedule his/her intake medications and/or appointments. The advantages of integration/separations of component functionalities are readily apparent to one ordinary skilled in the art, for example, separation of function in components enables the device to continue to operate will other components are being either replace/updated as taught by one of the applied reference, further separating components functions into separate devices, will enable a patient cost conscientious if desirable the option to select/purchase the device based on the desired functions need and his/her means.

Regarding claim 5, wherein the IMD and the communication module communicate with one another using radio-frequency telemetry (Nappholz: col 4/lines 6-9, and col 5/lines 15-19).

Regarding claim 6, wherein the communication module further comprises a microprocessor (Nappholz: 90 of Fig. 3), and one RF communications circuit for transmitting information to and receiving information from the IMD (Nappholz: 124 and 74/76 of Fig. 3).

Regarding claim 7, data output port, cable and connector for connection to a mobile telephone data input port of the mobile telephone (Nappholz: 62 of Figs. 3, 4 and 4B col 5/lines 25-34).

Regarding claim 8, a memory thereof computer readable software for initiating and maintaining communications with the mobile telephone using standardized handshake protocols (Nappholz: col 8/lines 19-25).

5. Claims 9 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith-Nappholz in view of Cox in further view of deCoriolis et. al. (US 5,342,408) (deCoriolis hereafter).

Regarding claim 9, however the above-mentioned prior is silent regarding telemetry signal strength indicator;

DeCoriolis teaches a telemetry system/method including a signal strength indicating means for providing an indication of received signal strength at an external mode (abstract).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the teachings of Smith for monitoring the parameter associated with the operation of the implanted device, as well as the patient health, the teachings of deCoriolis for the same objective would be readily apparent. One would be motivated to monitor the operation of the implanted device for assuring accuracy of the transmitted data provided by the implanted device, the external device's telemetry receiving circuitry must receive the maximum signal strength possible, thereby the need for an indication of the signal strength so that the reception circuitry may be properly programmed.

Regarding claim 10, wherein the communication module further comprises a memory for storing software downloaded to the IMD (Smith: col 12/lines 37-39).

Regarding claim 11, wherein the communication module comprises a battery (50A) or an I/O interface (44) supporting 20, 30, and 32 communication links (Nappholz: Fig. 1).

Regarding claim 12, wherein the communication module is adapted to receive electrical power from a portable energy source (50A) disposed to there within (Nappholz: Fig. 1)..

Regarding claim 13, however the above-mentioned prior art does not explicitly teach wherein the communication module is plug-and-play compatible with the mobile telephone.

Official Notice (*see MPEP § 2144.03 Reliance on "Well Known" Prior Art)* is taken that plug-and-play was old and well known in the Data Processing art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to include a plug-and-play application compatible with the mobile telephone because give motivation use add-in cards that are easy to install and use and take advantage of their extremely high memory capacities optimal for many mobile and portable applications (e.g. mobile telephones), such PC cards have become widely used for mass data storage applications, and are a popular alternative for conventional add-on card implemented non-volatile memory solutions such as rotating hard disks and battery-backed SRAM, especially for personal data assistants (PDAs).

Regarding claim 14, wherein the communication module (14), upon receiving instruction from the remote computer system or a remote health care provider (27), upload data therefrom (Nappholz; col 2/lines 41-45, col 2/lines 65-col 3/line 3, col 4/lines 11-20) or including means for interrogating the IMD from a remote computer system through the communication module (Nappholz; 13/lines 44-col 14/line 36).

Regarding claim 15, the wherein communication module (14) comprises means for storing information obtained from the IMD (12) in a memory (49 or 31) (Nappholz: col 7/lines 8-13 and col 8/lines 15-18, or memory (31) see col 8/lines 19-28).

Regarding claim 16, wherein the communication module (14) further comprises means for relaying information obtained from the IMD (12) to the remote computer (27) via the mobile telephone (14) over computer systems (26 or 8) (Nappholz: col 6/line 64-col 7/line 64).

Regarding claims 17-19, these claims are substantially the same as system claims 14-16, discussed above, same rationale of rejection is applicable.

Regarding claim 20, wherein the communication system (26 or 8) comprises a mobile, wireless or cellular based telephone network (Nappholz: col 4/lines 9-11 or col 7/lines 23-27).

Regarding claim 21, wherein the communication module (14) comprises means (106 of Fig. 3) for managing (storing and delivering) update software relating to the operational or functional parameters of the IMD (Nappholz; col 6/line 64-col 7/line 3, 50-64 and col 5/lines 57-60).

Regarding claim 22, wherein the communication module further comprises means for defecting a abnormal condition ("fault") in the operation or circuitry thereof (Nappholz: col 1/lines 23-31).

6. Claims 23 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith-Nappholz in view of Cox in further view of U.S. Patent No. 3,972,320 Kalman.

Regarding claim 23, however the above-mentioned prior art is silent with respect to correcting a detected fault in operation or circuitry of the communication module and means for notifying the remote computer system or the patient that the fault has been corrected.

Kalman teaches a system/method related medical devices (col 1/lines 5-11), including a device having means (10 of Fig. 1) for detecting a fault in operation or circuitry of itself and means (10 of Fig. 1) for notifying a remote computer system a fault needs to be corrected (col 5/lines 29-66 and col 25/lines 15-61).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the teachings of Smith for monitoring the performance of an IMD and the patient hosting said device through a communication device which acquires both patient and device status information for further transmission the remote physician and/health care providers locations, to assure that this intermediate device serving as point of relay with the external world is provide with fault tolerant measure. Thereby, the self-testing and notification mechanism taught the Kalman would be readily apparent. One would be motivated to enhance Smith systems with the teachings set for in Kalman reducing communication to a specific location only under predetermined condition is detected and generate specific alarm notification based on the detect fault being patient or device malfunction related and further notify for example a billing related remote computer that new or updated software has been downloaded to the implanted device for correcting detect fault for further account for software distribution services

Regarding claim 24, wherein the communication module comprises means for detecting a fault in the operation or circuitry of the IMD (Nappholz: col 1/lines 23-31).

Regarding claim 25, including limitations discussed on claim 23 and further wherein the communication module comprises means for correcting a detected fault in the operation or circuitry of the IMD (Nappholz: col 1/lines 23-31).

Regarding claim 26, means for obtaining ("mining") patient history or performance parameter integrity or software status from the communication module (Nappholz: col 7/lines 1-19).

7. Claims 27 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith-Nappholz in view of Cox in further view of KROLL et. al. (US 5,258,906) (Kroll hereafter) .

Regarding claim 27, however the Smith and the Nappholz references are silent regarding the generation of invoices in their systems;

Kroll teaches a system/method related to medical device systems, including the generation of invoices in such systems. Kroll teaches a communication device (12 of Fig. 1) comprising an invoice generating entity communicatively coupled to a medical device (21 of Fig. 1) (col 3/lines 21-49), the invoice generating device configured to generate an invoice (col 3/line 62-col 4/line 14, col 5/lines 8-15, 43-68), when communication between the medical device is initiated the communication device invoicing entity (col 4/lines 41-63).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the teachings of Smith for monitoring an implanted medical device in a patient, and communicating with physicians and health care personal, the teachings of Kroll for providing an invoice generation mechanism related to these services would be readily apparent. One skilled in the art would be motivated given the transmission mechanism, self-contained modularity and add-on capability of the Smith-Nappholz system to further include the generation and transmission of formatted invoices for processing and delivering for the remuneration of rendered services based on actual metered usage of the device systems including for example the implanted device and the mobile telephone.

Regarding claim 28, the communication module comprises means for monitoring the performance of the IMD or for monitoring physiologic signals or data indicative of the patient's health status (Nappholz: col 1/lines 23-31).

Regarding claim 29, this system claim is substantially the same as claim 1 combined with claim 2 or 3, same rationale of rejection is applicable.

Regarding claim 30, this is in substance the same as claim 2, discussed above, same rationale of rejection is applicable.

Regarding claim 31, this is in substance the same as claim 3, discussed above, same rationale of rejection is applicable.

Regarding the system claims 32-49, 50-54 and 55 are substantially the same as the system claims 5-23, 24-27 and 28, respectively, wherein the communication module in the latter further comprises either the features of claim 2 or 3, same rationale of rejection is applicable.

Citation of Pertinent Art

8. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Copies of Non-Patent Literature documents cited will be provided as set forth in MPEP§ 707.05(a):

4,811,390

Garabedian teaches a control system including means capable of performing simultaneous bi-directional communication operation of a mobile telephone.

5,383,912

Cox et. al. teach an implantable medical device capable of simultaneous bi-directional communication with a communication module located external to the patient's body (col. 2, lines 32-43 & col. 5, lines 12-39).

5,657,374

Russell et. al. teaches a cellular communications system with centralized base stations and distributed antenna units, comprising: a method of communicating a *plurality of two-way inbound/outbound cellular telephone transmissions* between a base station and a physically remote cell using a set of channels. At the base station, a *plurality of outbound telephone transmissions, received from a network*, are analog modulated onto respective ones of RF analog outbound channel carriers. The modulated analog channel carriers are combined to form a single RF analog outbound signal representing all of the outbound telephone transmissions in the set of channels. The analog outbound combined signal is subsequently digitized into a single stream of outbound digital samples and transmitted to the remote cell. At the remote cell, the stream of digital samples is converted back to the *RF analog outbound combined signal and broadcasted directly to mobile units in the cell.* Further, the remote cell receives a *plurality of simultaneous inbound telephone transmissions from the mobile units as an RF analog inbound* combined signal. The analog inbound combined signal is digitized into a single stream of inbound digital samples and transmitted to the base station. At the base station, the stream of inbound digital samples is converted into a single RF analog inbound signal, the inbound telephone transmissions are recovered from the single RF analog inbound signal, and delivered to the network.

5,721,762

Sood discloses a shared base stations for voice and data cellular telecommunications and method, comprising: a communication system capable of simultaneous calls handled on a number of cellular broadcast frequencies, both analog and digital systems provide multiple "cellular channels" for handling multiple simultaneous cellular calls. A "cellular channel" means a two-way radio telecommunications link capable of carrying a cellular call between users of a cellular network. Time-division multiplexing using the current TDMA standard permits a single radio frequency pair to carry three independent telephone calls simultaneously. Consequently, each transceiver in a base station is capable of handling three separate cellular channels simultaneously. Analog systems carry one cellular channel per transceiver.

4,705,043

Imran teaches an implantable medical device capable of simultaneous bi-directional communication with a communication module located external to the patient's body (abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prieto, B. whose telephone number is (571) 272-3902. The Examiner can normally be reached on Monday-Friday from 6:00 to 3:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Andrew T. Caldwell can be reached at (571) 272-3868. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3800/4700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, status information for published application may be obtained from either Private or Public PAIR, for unpublished application Private PAIR only (see http://pair-direct.uspto.gov or the Electronic Business Center at 866-217-9197 (toll-free).

Any response to this action should be mailed to:
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(703) 872-9306 (old No. in service until Sept. 15, 2005),
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TC 2100
Primary Examiner
July 29, 2005

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